REMARKS

As a preliminary matter, applicants acknowledge the Examiner's request for the applicants to inform the Examiner how this application differs from its parent and the Examiner's request for a listing of all related cases (allowed, abandoned, and pending) and the claims in each of the same.

With respect to the Examiner's request for the identification of the new matter in this application, the Examiner states only that the request is to "determine the proper priority date," which applicants surmise is for the new matter incorporated into this application. Under this rubric, it appears that the Examiner is requesting this information so that he may apply art against the claimed invention that post-dates the November 29, 2000, priority date for this application. Applicants respectfully submit that the Examiner's request, regardless of its purpose, is in direct violation of the mandates of the Patent Statute. On this matter, applicants direct the Examiner's attention to MPEP § 201.09, which provides the following guidance on the application of priority dates to continuation-in-part applications:

> ...an alleged continuation-in-part application should be permitted to claim the benefit of the filing date of an earlier nonprovisional application if the alleged continuation-in-part application complies with the requirements of 35 U.S.C. § 120:
>
> (A) The first application and the alleged continuation-in-part application were filed with at least one common inventor;
>
> (B) The alleged continuation-in-part application was "filed before the patenting or abandonment of or termination of proceedings on the first application or an application similarly entitled to the benefit of the filing date of the first application"; and
>
> (C) The alleged continuation-in-part application "contains or is amended to contain a specific reference to the earlier filed application." *See*, 37 C.F.R. § 1.76.

Because the instant application shares two of the same inventors as its parent application (U.S. Patent Application Serial No. 09/751,666) and its grandparent application (U.S. Patent Application Serial No. 09/727,391), was filed before the abandonment of its parent application, and includes a specific reference to both its parent and grandparent application in the text of the specification, this application is entitled to its November 29, 2000, priority date. Because the Examiner is statutorily prohibited under 35 U.S.C. § 120 from establishing a later priority date for any new matter in this application, applicants must respectfully refuse to inform the Examiner how this application differs from its parent.

With respect to the Examiner's request for a listing of all related cases and their claims, applicants note that this request appears to be a request for information pursuant to 37 C.F.R. § 1.107, albeit it is not identified as such. In response to this request, applicants would like to note that because the requested information is readily available to the Examiner through USPTO files and databases,

applicants are of the opinion that the Examiner's request for information does not appear to be justified under the rules (please *see*, MPEP § 704.11, which sets forth the situations where a request for information is justified). Notwithstanding the foregoing, applicants are nonetheless responding to the Examiner's request by attaching to the end of this paper a copy of the continuity data pages from the PAIR database for this application and a listing of the claims from each of the applications identified therein. With respect to the listing of the claims, applicants note that because all of the cases in this patent family are pending or abandoned (none are allowed yet), applicants are providing the claims as filed for each application. Applicants submit that the information provided herewith is fully responsive to the Examiner's request under 37 C.F.R. § 1.107.

THE CLAIM AMENDMENTS:

Claim 1 has been amended to change the term "localized volume" to "localized fluid volume." This change is made solely to clarify that the "localized volume" recited in claim 1 is the same as the "localized fluid volume" defined on page 10, lines 25, to page 11, line 10, of the specification.

Claim 1 has also been amended to specify that the localized volume is ejected towards a "suitable substrate material"; support for the term "suitable substrate material" and examples of such are set forth in the specification at page 14, line 16 to page 15, line 14.

Claim 14 has been amended to clarify that the data inputted from steps (a) and (b) is the acoustic impedances and the properties, respectively. Support for the amendment to claim 14 is found in claim 1 and in the specification at, *inter alia*, page 17, lines 4-7; page 36, lines 19-24; page 37, lines 11-13; page 41, line 18, to page 42, line 16; page 48, lines 6-8; and Examples 1 and 2.

Claim 15 has been amended to change the term "circumscribed volume" to "circumscribed fluid volume." This change is made solely to clarify that the "circumscribed volume" recited in claim 15 is the same as the "circumscribed fluid volume" defined on pages 11, lines 11-28, of the specification.

Claims 71, 72, and 79 have been reworded to more clearly define the invention. Support for the change to claim 71 is found in the specification at, *inter alia,* page 6, line 28, page 7, lines 1-2, and page 11, lines 12-13. Claim 72 merely rewords the language in the claim and does not add anything over that found in the claim as filed. Similarly, claim 79 has been reworded to include the language from step (b) of claim 1 and thus, does not add anything over that found in claim 1 as filed.

Claim 76 has been amended to remove the second incident of the word "single."

As all claim amendments are fully supported by the application as filed, no new matter has been added to the application with the claim amendments submitted in this paper.

THE NON-STATUTORY DOUBLE PATENTING REJECTION:

Claims 1-7 and 71-73 stand rejected under the judicially created doctrine of obviousness-type double-patenting over claims 1, 10, and 11 of co-owned U.S. Patent No. 6,642,061 to Ellson ("Ellson '061"). This rejection is respectfully traversed.

As noted by the Examiner, a non-statutory double-patenting rejection is a judicially-created public policy doctrine designed to prevent the improper extension of a patent's claims. In the instant case, the Examiner fears that issuance of the claimed invention will result in an improper extension of the Ellson '061 Patent. The following discussion will explain why the claims of the instant application will not serve to extend the patent grant of Ellson '061.

As recited in claim 1, the present invention relates to a separation method comprising the steps of (a) detecting, in a fluid having a surface and containing a plurality of localized fluid volumes having a different acoustic impedance than the fluid, a single localized volume located sufficiently near the surface for ejection; (b) determining whether the single localized volume possesses one or more properties; (c) selecting the single localized volume for ejection from the fluid based on the determination of one or more properties in step (b); and (d) ejecting the single localized volume from the fluid by use of focused radiation.

As recited in claim 1, Ellson '061 relates to a method for acoustically generating a droplet, comprising (a) providing a reservoir containing (i) a lower layer comprised of a first fluid, and (ii) an upper layer having a nonuniform thickness and comprised of a second fluid, wherein the first and second fluids are immiscible; and (b) applying focused acoustic energy to the reservoir in a manner effective to eject a droplet from the reservoir, wherein the droplet is comprised of a predetermined volume of the first fluid propelled through the upper layer at an aperture region that exhibits a local thickness minimum.

The Examiner asserts that the claimed invention is not patentably distinct over Ellson '061 because Ellson '061 includes an aperture and a biomolecule whereas the claims of the instant application include different acoustic impedances. While the Examiner is correct that Ellson '061 includes an aperture and a biomolecule and the claims of the instant application include different acoustic impedances, the invention of Ellson '061 and the claimed invention are much more complicated and much more distinguishable over each other than the Examiner suggests. The following discussion will demonstrate how and why the claimed invention is patentably distinct over Ellson '061.

As noted above, Ellson '061 claims a method for generating a droplet comprising a two-layered reservoir with immiscible fluids, where a droplet is acoustically ejected through the fluids (where the local thickness minimum is zero, there will be one layer of fluid, rather than two). In Ellson '061, the fluids are layered, not encapsulated; accordingly, there is no localized volume to speak of in Ellson '061.

Further, in Ellson '061, upon application of the focused acoustic energy to the fluids, a droplet forms, which is subsequently ejected from a local region of the fluids, i.e., the aperture region. As noted by the Examiner, the droplet of Ellson '061 may include a biomolecule (claim 10) and that the biomolecule may include DNA, RNA, antisense, oligonucleotides, peptides, proteins, ribosomes, and enzyme cofactors (claim 11). While the Examiner asserts that the biomolecule of Ellson '061 includes a cell, applicants note that Ellson '061 does not disclose this to be the case (*see*, the definition of "biomolecule" at col. 6, lines 20-34 of Ellson '061; also, *see*, this identical definition in the specification of the instant application at page 13, line 22, to page 14, line 2, and compare this definition to the definitions provided for the "localized fluid volume" and the "circumscribed fluid volume" at page 10, line 26, to page 11, line 28 of the specification).

In contrast to Ellson '061, the instant application claims a separation method comprising the acoustic ejection of a localized volume from a fluid. Thus, unlike Ellson '061, the fluid of the claimed invention, in its starting state, necessarily includes a localized fluid volume, which is subsequently detected and ejected from the fluid. Further, while the application of the focused acoustic energy in Ellson '061 *generates the droplet*, the application of the focused radiation of the present invention *separates the localized fluid volume from the surrounding fluid.* Accordingly, as the foregoing discussion demonstrates, Ellson '061 and the instant application are claiming two distinguishable methods that do not read upon each other.

In short, Ellson '061 is claiming a striated fluid from which an droplet is generated (and which may contain a biomolecule) and pushed through the fluid while the instant application is claiming an encapsulated localized fluid volume (which may be a cell or a solid or gel particle), which is first detected and then extracted from a surrounding fluid.

The foregoing discussion demonstrates that the invention of Ellson '061 differs significantly from the invention claimed in the instant application. As a result of the differences between Ellson '061 and the claimed invention, applicants submit that the claimed invention is patentably distinct over Ellson '061. Because issuance of the instant application will not result in an extension of the patent grant of Ellson '061 for the reasons discussed above, applicants respectfully request reconsideration and withdrawal of this non-statutory double-patenting rejection.

OBVIOUSNESS REJECTION UNDER 35 U.S.C. § 103(a):

The claims stand rejected under 35 U.S.C. § 103(a) as obvious over Ellson '061. This rejection is respectfully traversed.

As a preliminary matter, applicants note that the Office Action specifies that claims 1, 2, 5, and 48 of this application stand rejected as obvious. Because it is clear to applicants that the Examiner repeated this rejection from this application's sister, identified by U.S. Patent Application Serial No. 09/999,166, applicants are addressing this rejection generally without reference to any particular claim.

As noted by the Examiner, Ellson '061 represents prior art under 35 U.S.C. § 102(e); accordingly, Ellson '061 invokes the common ownership provision of 35 U.S.C. § 103(c), which reads as follows:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention, were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The inventors of Ellson '061 are Ellson, Mutz, and Foote; accordingly, Ellson '061 and the instant application share two common inventors: Ellson and Mutz. Ellson '061 was filed on March 22, 2002, and claims priority to its ultimate parent application, U.S. Patent Application Serial No. 09/669,194, filed September 25, 2000, now abandoned. The instant application was filed on November 29, 2001, and claims priority to its parent application, U.S. Patent Application Serial No. 09/727,391, filed on November 29, 2000, now abandoned. The invention described in Ellson '061 and the invention described in the instant application have been at all times owned by the same entity, Picoliter Inc., now Labcyte Inc.

As this application and Ellson '061 were commonly owned at the time of the invention of the subject application, this rejection may be overcome with a statement of common ownership. This statement is made in a clear and conspicuous manner according to the guidelines set forth in MPEP § 706.02(l)(3).

STATEMENT OF COMMON OWNERSHIP

The application upon which U.S. Patent No. 6,642,061 (Ellson '061) was based (Ellson '061 is a continuation-in-part of U.S. patent application Ser. No. 09/962,730, filed Sep. 24, 2001, now U.S. Pat. No. 6,548,308 which is a continuation-in-part of U.S. patent application Ser. No. 09/669,194, filed Sep. 25, 2000, now abandoned) and the instant application (U.S. Patent No. 09/999,166) were, at the time the invention of the instant application was made, owned by the same company, Picoliter Inc., now Labcyte, Inc.

With the foregoing Statement of Common Ownership, Ellson '061 is eliminated as prior art under 35 U.S.C. § 103(a) over the claimed invention. Accordingly, applicants respectfully request reconsideration and withdrawal of this obviousness rejection.

ENABLEMENT REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 1-15 and 67-88 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabling. This rejection is respectfully traversed.

The standard for determining if a claim is enabling is whether the experimentation needed to practice the invention is undue or unreasonable. *See, Mineral Separation v. Hyde*, 24 U.S. 261, 271 (1916) as cited in MPEP § 2163.07(b). The Federal Circuit has held that several factors must be considered when making an enablement determination; these factors are identified as the *Wands* factors after the case, *In re Wands*, 858 F.2d 731, 737. In this rejection, however, the Examiner did not apply the *Wands* factors.

The Examiner is asserting that the claimed invention is exclusive to the ejection of a live cell from a fluid onto a substrate without killing the cell and thus, must claim the features as specified by the Examiner.

In light of the standard for determining enablement as set forth above, it appears that the Examiner is using this rejection to argue that the ordinary artisan could not practice the claimed method with a localized volume other than a live cell without undue experimentation. Applicants have reviewed the *Wands* factors in light of the language of the Examiner's rejection and have come to the conclusion that the Examiner's rejection appears to be taking issue with the "breadth" of applicants' claims.

The following discussion will demonstrate that the Examiner's position is completely unjustified in light of the disclosure in the instant application.

As a preliminary matter, applicants note that the present invention as claimed is ***not*** specific to the ejection of a living cell from a fluid onto a substrate surface without killing the cell; the invention as

claimed relates to the ejection of a *localized volume* from a fluid towards a substrate wherein the localized volume has a different acoustic impedance from that of the fluid.

Turning to the enablement issue at hand, with respect to the breadth of the claimed "localized fluid," applicants note that while live cells are certainly contemplated as one example of a localized volume that may be ejected from the fluid, the claimed separation method is not exclusive to live cells or to cells in general. For example, at page 10, line 25, to page 11, line 28, of the specification, several examples of localized volumes other than cells (both living or not living) contemplated under the invention are disclosed, these include all of the following: uncircumscribed localized volumes, such as sugar crystals, fluid compositions wherein a lipid/hydrophobic region is contained in a hydrophilic fluid, and fluid compositions wherein a hydrophilic region is contained in a lipidic/hydrophobic fluid; and circumscribed localized volumes, such as platelets, mitochondria, nuclei, fluid-containing microcapsules, solid or gel particles such as glass or polymer beads, liposomes, micelles, and reverse micelles. Further, at Example 6, bacteria are disclosed as another example of a localized volume that may be used in the claimed separation method.

The foregoing list of examples provides the ordinary artisan with a sufficient disclosure to make and use the claimed separation method with localized volumes over and beyond "live cells" without undue experimentation. Accordingly, the breadth of the claimed separation method is not limited to "live cells" as asserted by the Examiner.

Because the claimed invention is fully supported by the disclosure and enables the ordinary artisan to make and use the invention as claimed, applicants respectfully request reconsideration and withdrawal of this rejection.

INDEFINITENESS REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

Claims 1-15 and 67-88 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. In particular, the Examiner identifies objectionable language in claims 1(a), 14, 71, 79, and 81. This rejection is respectfully traversed for claims 1(a), 71, 79, and 81.

It is well-established that the meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. *See*, MPEP § 2173.05. When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation on the prior art. *See, e.g., In re Zeltz*, 893 F.2d 319 (Fed. Cir. 1989) as cited in MPEP § 2173.05.

With respect to the rejection of the term "localized volume" in claim 1, applicants note that this term is expressly defined in the specification at page 10, line 26, to page 11, line 11. Similarly, the rejection of the term "circumscribed volume" in claim 71 is also expressly defined in the specification at page 11, lines 11-18. Accordingly, the Examiner must examine these terms as they are defined and cannot reject them merely because they are not "terms of art" as specified by the Examiner. With respect to the Examiner's reference to terms of art, applicants note that the Federal Circuit's predecessor court endorsed the use of new terms in claims in 1970. *See, e.g., In re Fisher*, 427 F.2d 833 (CCPA 1970) as cited in MPEP § 2173.05. The MPEP also endorses the use of new claim terms, not only by citing *In re Fisher*, but also by noting that "[n]ew claim terms are often used when a new technology is in its infancy or is rapidly evolving." MPEP § 2173.05 (8th ed., Rev. 1, p. 2100-201). Thus, where the definition in the specification apprises the ordinary artisan of the utilization and scope of the invention with language as precise as the subject matter permits, an indefiniteness rejection under 35 U.S.C. § 112, second paragraph, is not proper. *See*, MPEP § 2173.05, p. 2100-201.

Notwithstanding the foregoing, for the sake of clarity, applicants have amended claim 1 so that the first incident of the term "localized volume" has been amended to "localized fluid volume," which is how this term is identified in the definition on pages 10-11 of the specification. Similarly, applicants have amended claim 15 so that the first incident of the term "circumscribed volume" has been amended to "circumscribed fluid volume," which is how this term is identified in the definition on page 11 of the specification.

The recitation of the term "data" in claim 14 was rejected as lacking antecedent basis. Claim 14 has been amended to delete the term "data." Support for the change to claim 14 is identified above in the discussion of the claim amendments.

With respect to the rejection of the term "circumscribed" from claim 71 as lacking antecedent basis, applicants direct the Examiner's attention to claim 15, where the term "circumscribed" is used in reference to the "circumscribed fluid volume." Applicants submit that this recitation provides an antecedent basis for the term "circumscribed volume" in claim 71. Notwithstanding the foregoing, applicants have reworded claim 71 to more clearly define the invention as recited therein. Support for the change to claim 71 is identified above in the discussion of the claim amendments.

With respect to the rejection of the term "the determination" from claim 79 as lacking definite antecedent basis, applicants have amended claim 79 to exactly match the language used in claim 1(c), which was not rejected by the Examiner as indefinite. Because claim 79 ultimately depends from claim 1, the recitation of "the determination of one or more properties in step (b)" has a fully supported antecedent basis in steps (b) and (c) of claim 1.

With respect to the rejection of the term "the geometric center of the volume" from claim 88 as lacking antecedent basis, applicants direct the Examiner's attention to the recitation of "a geometric center of the volume" in claim 87, which provides a definite antecedent basis for the objected-to term.

THE OBJECTION TO THE TITLE:

The Examiner has objected to the title of the invention as not descriptive. Applicants have amended the title of the invention to:

FOCUSED ACOUSTICS FOR DETECTION AND SORTING OF FLUID VOLUMES

THE PRIOR ART NOT RELIED UPON:

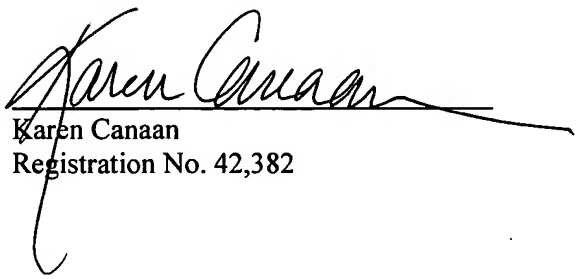
Applicants have reviewed the prior art not relied upon and acknowledge that the references are sufficiently removed from the present invention so as not to be applied against the claimed subject matter.

CONCLUSION:

Each of the Examiner's requests and rejections have been fully addressed in this paper. Because the foregoing amendments and remarks demonstrate that the claimed invention is clearly defined, enabling, claims a separately patentable invention from Ellson '061, and is not rendered obvious by Ellson '061, applicants respectfully request reversal of all rejections set forth in the Office Action under reply and early passage of this application to issue.

If the examiner has any questions regarding this Amendment that may be addressed by way of a telephone call or-mail correspondence, he is encouraged to contact the undersigned at 650-330-4913 or at canaan@reedpatent.com.

Respectfully submitted,

By: 

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